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Subject: Environmental Defense comments on Sunset Yellow (CAS# 2783-94-0)

(Submitted via Internet 7/22/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and tadams@therobertsgroup.net)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Sunset Yellow (CAS# 2783-94-0).

The test plan and robust summaries for Sunset Yellow were submitted by the International Association of Color Manufacturers. This submission is very similar to a previous submission on C.I. Acid Yellow, so many of our comments are the same.

According to the sponsor, Sunset Yellow is a water-soluble azo dye used as a food colorant in dairy products, snack foods, cereals, bakery items, confectionery products, frozen desserts, beverages, cosmetics, ingested and externally applied drugs and dietary supplements. These uses are approved by the FDA, and Sunset Yellow has also been evaluated for safety by the WHO Committee for the Evaluation of Food Additives (JEFCA). JEFCA established an average daily intake of up to 2.5 mg/kg/day in 1982. No information was provided on environmental releases of Sunset Yellow as a consequence of its manufacture or use in foodstuffs.

According to the test plan, FDA has established upper limits for several toxic impurities in Sunset Yellow, although it is not clear when those upper limits were established. We are concerned with those impurities, as they include arsenic (3 ppb), benzidine (1 ppb), lead (10 ppm) and mercury (1 ppm). Has a recent survey been conducted that would permit reliable estimates of the intake of these toxicants from the use of azo dyes as food additives in the U.S. population, particularly children? Mercury and lead are potent developmental toxicants and arsenic and benzidine dyes have been classified as known human carcinogens. We request that the amounts of mercury, lead, arsenic, benzidine and the other toxicants in Sunset Yellow be quantified and made publicly available. The levels allowed by FDA seem too high, particularly for mercury and lead, given increased understanding of the toxic effects of these metals and since significant numbers of people are already exposed to these toxic metals at levels higher than considered safe.

The sponsor concludes that existing data are adequate for all SIDS endpoints. While we agree with this contention for mammalian health endpoints, we do have some concerns that need to be addressed before we make a final recommendation. There are several repeat dose studies available, including long-term cancer bioassays and reproductive and developmental studies. Some of the studies were conducted by the NTP and they are well-described in the test plan and robust summaries. However, the test substances have not been adequately characterized in the robust summaries. What were the levels of the toxic impurities discussed in the above paragraph, and are those levels consistent with the amounts generally

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found in Sunset Yellow added to various foodstuffs? Also, is there any information available on the mechanism by which Sunset Yellow and C.I. Acid Yellow caused the chromosomal aberrations observed in at least one of the tests for genetic toxicity?

We also have concerns regarding the adequacy of the data provided for aquatic toxicity. The sponsor uses ECOSAR estimates along with experimental data from proposed surrogates to address all three aquatic toxicity endpoints. The surrogate data are from stilbene sulfonic acids, but these proposed surrogates have significantly different chemical structures than Sunset Yellow. For example, they do not contain a diazo moiety and the aromatic rings differ in number as well as position. We also note that there is a very wide range of ECOSAR estimates for LC50 values for different stilbene sulfones (200-10,000 mg/kg), and it is doubtful if ECOSAR models are appropriate for estimating aquatic toxicities of Sunset Yellow and other azo dyes. Therefore, we recommend that at least a fish or aquatic invertebrate toxicity study be conducted on Sunset Yellow, and if the result differs significantly from the ECOSAR estimate, then studies need to be conducted on the other aquatic toxicity endpoint. We do concur with the sponsor that the algal toxicity data are adequate for HPV purposes and indicate a low order of toxicity for this endpoint.

Thank you for this opportunity to comment.

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